MAR 1 4 2002

K013572

510(k) Summary

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Mitek Products is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Mitek Products chooses to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

The summary regarding the adverse health effects of the modified device, Mitek Biocryl Interference Screws is as follows:

Trade Name:	**Mitek Biocryl Interference Screws**
Sponsor:	Mitek Products 249 Vanderbilt Avenue Norwood, MA 02062 Registration #1221934
Device Generic Name:	Bone Fixation Screw
Classification:	According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.
Product Code:	87 HWC
Predicate Devices:	**K990454 Bio-Interference Screw** **K993975 Absolute Absorbable Interference Screw** **K993630 BioLok®Screw** **K002070 BioLok® Screw**

Device Description: The device described in this 510(k) is sterile, disposable implant designed to secure soft tissue to bone. The Mitek Biocryl Interference Screws are indicated for the fixation of soft tissue grafts or bone-tendon-bone grafts during cruciate ligament reconstruction surgeries of the knee.

Safety and Performance:
This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Mitek has provided certification of compliance to 21 CFR 820.30 Design Control requirements, descriptions of Mitek's Design Control and Risk Analysis procedures, and the results of validation testing (performance testing) for the device modification.

Conclusion:
Based on the indications for use, technological characteristics, and comparison to predicate devices, the Mitek Biocryl Interference Screws have been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2002

Ms. Christine Kuntz-Nassif
Regulatory Affairs Project Manager
Mitek® Products
249 Vanderbilt Avenue
Norwood, MA 02062

Re: K013572
Trade/Device Name: Mitek Biocryl Interference Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: February 11, 2002
Received: February 12, 2002

Dear Ms. Kuntz-Nassif:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

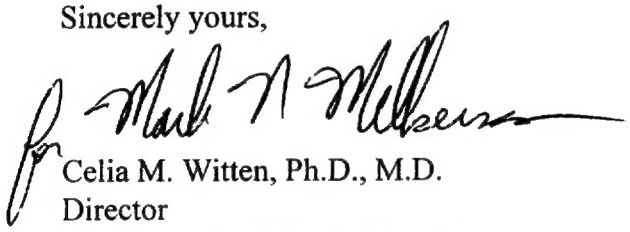
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013572

Device Name: Mitek Biocryl™ Interference Screw

Indications for Use:

The Mitek Biocryl Interference Screw is indicated for the fixation of soft tissue grafts or bone-tendon-bone grafts during cruciate ligament reconstruction surgeries of the knee

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013572

Prescription Use Yes OR Over-the -Counter Use No
(Per 21 CFR 801.109)